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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA,)	No. CR 15-234 CRB
)	No. CR 16-225 CRB
Plaintiff,)	
)	GOVERNMENT’S BRIEF REGARDING SCOPE
v.)	OF 18 U.S.C. § 1001
)	
DAVID MILLER and MINNESOTA)	
INDEPENDENT COOPERATIVE, INC.,)	
)	
Defendants.)	

The government submits this brief in response to the Court’s questions regarding the scope of 18 U.S.C. § 1001. Section 1001(a) contains three subsections, each of which prohibits distinct conduct. None requires that any statement be made directly—or even indirectly—to a government agent or agency. Subsection 1001(a)(2), for example, prohibits making “any materially false, fictitious, or fraudulent statement or representation” regarding “any matter within the jurisdiction of the executive . . . branch.” The Ninth Circuit has explained that, for purposes of subsection 1001(a)(2), the “false statement need not be made to a federal agent to support a conviction.” *United States v. King*, 660 F.3d

1 1071, 1081 (9th Cir. 2011). While “jurisdiction” is not defined in the statute, “the most natural,
2 nontechnical reading of the statutory language is that it covers all matters confided to the authority of an
3 agency or department.” *United States v. Rodgers*, 466 U.S. 475, 479 (1984). Moreover, “jurisdiction” is
4 construed broadly to protect “the integrity of official inquiries.” *Bryson v. United States*, 396 U.S. 64,
5 70 (1969). The statute is intended to cover “those deceptive practices which might result in the
6 frustration of authorized government functions,” *United States v. Green*, 745 F.2d 1025, 1210 (9th Cir.
7 1984) (citation omitted), and it requires a “direct relationship” between the authorized functions of an
8 agency and the false statement, *United States v. Facchini*, 874 F.2d 638, 640-41 (9th Cir. 1989) (en
9 banc).

10 Count 12 of the Ohio Indictment (Case No. 16-225) charges conspiracy to “knowingly and
11 willfully make and use a false document, knowing such document to contain materially false, fictitious,
12 and fraudulent statements and entries, in a matter within the jurisdiction of the FDA, an agency within
13 the executive branch of the United States.” While the indictment does not specify which subsection of
14 Section 1001 is implicated, the language in the indictment directly quotes Section 1001(a)(3). The
15 Ninth Circuit, addressing Section 1001(a)(3), has held that the documents in question need not ever be
16 submitted to a federal agency to establish criminal liability. *United States v. Balk*, 706 F.2d 1056 (9th
17 Cir. 1983). *Balk* concerned the United States Navy’s requirement “that welders and welding procedures
18 used by its contractors be certified as meeting certain specifications.” *Id.* at 1058. The certifications
19 themselves were issued by a private testing company. *Id.* The defendants were charged with making
20 and using false documents in the course of seeking that certification. *Id.* The Ninth Circuit explained
21 that in order to sustain a conviction under Section 1001(a)(3), “the falsified documents did not have to
22 be submitted to the Navy; it is only necessary that their intended use be related to a matter within the
23 jurisdiction of the Navy.” *Id.* at 1059. As to the Navy certification, the “importance of the falsified
24 documents was that they were necessary to obtain work as a Navy contractor,” and the Ninth Circuit
25 concluded that “[t]his is clearly a matter within the jurisdiction of the Navy within the meaning of
26 section 1001.” *Id.*

27 The government’s theory of the case fits squarely within the confines of *Balk*, and it does not
28 seek to break new ground. The pedigrees at issue in this case are clearly “related to a matter within the

jurisdiction” of the FDA. Indeed, not only did federal law require the preparation of pedigrees, FDA regulations (applicable at the time) provided that “[a]ny person required to create . . . records under [the Prescription Drug Marketing Act (PDMA)] . . . shall make them available, upon request, in a form that permits copying or other means of duplication, to FDA or other Federal, State, or local regulatory and law enforcement officials for review and reproduction.” *See* 21 C.F.R. § 203.60. The PDMA required wholesale distributors to create pedigrees for their customers, and thus federal law required that the pedigrees be provided to FDA upon request.

In addition, this Court has previously recognized that “[e]ven false statements made to non-governmental entities can subject a person to section 1001 liability provided such statements have a ‘direct relationship with an authorized agency function.’” *United States v. Townsley*, 2011 WL 1812599, at *3 (N.D. Cal. May 12, 2011) (Breyer, J.). As this Court went on, “[t]he phrase ‘direct relationship’ is also liberally construed, and the Ninth Circuit has held that ‘[t]o establish jurisdiction under 18 U.S.C. § 1001, it is only necessary that the statement relate to a matter in which a federal agency has the power to act.’” *Id.* (quoting *United States v. Boone*, 951 F.2d 1526, 1544 (9th Cir. 1991)). While this Court in *Townsley* dismissed the 1001(a)(2) counts, it did so because the false statements in that case were insufficiently tied to an agency’s function. Here, by contrast, not only does the charge relate to a different subsection, the creation of the document in question was directly mandated by law and required to be made available to the FDA upon request.

Lastly, the government notes that the evidence will show that defendants did indeed submit a false pedigree to the executive branch. Exhibit 690, appended to this brief, is a letter from Minnesota Independent Cooperative to the Consumer Protection Branch of the Department of Justice. The letter is dated July 12, 2012, and it concerns an incident in which a bottle of Viread (used to treat chronic hepatitis B) supplied by MIC contained the wrong medication—not simply the wrong dose, but an entirely different medication, manufactured by an entirely different pharmaceutical company. The letter attached a copy of a pedigree associated with the sale. That pedigree falsely states that the source of the

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Viread was B&Y Wholesale Distributors. The government anticipates introducing Exhibit 690 this week.

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Respectfully submitted,

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FIRST AMENDED PROPOSED JURY INSTRUCTIONS
CR 15-234 CRB; CR 16-225 CRB